

REMARKS

The Official Action of October 6, 2006, and the prior art relied upon therein have been carefully reviewed. The claims in the application are now claims 1-8 and 16-21, and the non-elected claims should be rejoined and all the claims should be allowed for reasons pointed out below. Applicants accordingly respectfully request favorable reconsideration and allowance.

Acknowledgement by the PTO of the receipt of applicants' papers filed under Section 119 is noted.

The restriction requirement based on lack of unity of invention has been maintained, whereby claims 3, 4 and 9-15 have been withdrawn. As previously noted in applicants' Reply of July 12, 2006, the Amaike publication does not anticipate applicants' claims, whereby claim 1 constitutes a single general inventive concept which exists throughout all four (4) of the groups, providing the same or corresponding special technical features. Why the Amaike publication does not anticipate is explained below.

Applicants accordingly respectfully reserve the right to petition the restriction requirement.

New claims 16-21 have been added. These are partly structural and partly product-by-process, and are patentable for the same reasons as the other claims, as pointed out below.

The misspelling of hyaluronic acid helpfully pointed out by the examiner has been corrected above.

Claims 2 and 5-8 have been objected to as being in improper dependent form. Appropriate correction has been required. The objection and requirement are respectfully traversed.

As regards dependent claims beginning with the article "A" instead of the article "The", there are certainly hundreds of thousands of U.S. patents (if not millions) with dependent claims starting with the article "A" instead of the article "The". Undersigned conducted a quick search in the "USPTO Patent Full-Text and Image Database" on January 5, 2007, for U.S. patents containing at least one claim containing the wording "A fiber according to claim 1", and this quite limited search turned up over 2000 U.S. patents containing at least one such claim. A copy of the printout of the first 50 hits is attached as attachment A.

This proves that there is no impropriety in beginning a dependent claim with "A" instead of "The". Applicants know of no authority for such an objection and requirement, and the PTO has cited no authority. The objection is simply not justifiable.

Nevertheless, as it really makes no difference whatsoever if dependent claims start with "A" or "The", applicants have amended the preambles of claims 2 and 6-8, in deference to the examiner's views, to insert "The" in place of "A". However, such an amendment would not be proper for claim 5 which has a different preamble than claim 1 upon which it depends, i.e. there would be no direct

antecedent basis in claim 5 for reciting "The three dimensional scaffold..." .

Applicants request that the objection and requirement by withdrawn.

Claim 1 has been rejected under the second paragraph of §112 as being indefinite in the recitation of "hybrid fibers" and further in reciting "the form thereof..." . These rejections are respectfully traversed.

Applicants believe that neither the terms "hybrid" nor "form" would be unclear to those skilled in the art. For example, the term "hybrid" appears to be art-recognized, noting for example document AD entitled "Hybrid Fiber and Membrane and Its Manufacturing Method". The word "form" is simply a synonym for "shape".

Accordingly, in deference to the examiner's views, and because it makes no difference in the scope of the claims, the word "hybrid" has been deleted and the word "form" has been replaced with the word "shape".

Withdrawal of these rejections is in order and is respectfully requested.

Claims 1 and 5-8 have been rejected under §102 as anticipated by Amike et al, reference U (Amike). This rejection is respectfully traversed.

First, Amaike relates to and discloses a fiber structure which is a polyion complex of chitosan and gellan. On the other

hand, the present invention relates to a chitosan/acidic biopolymer fiber. As understood, gellan, which is a component of Amaike, is not an acidic biopolymer, and therefore Amaike does not anticipate claim 1 or any of applicants' claims. Attached as attachments B and C are two definitions of "gellan" taken off the web.

In addition, it should be clear from the respective methods of preparation that applicants' claimed fiber is quite different from that of Amaike. Thus, Amaike describes the preparation of the fiber as follows (page 288, left column, emphasis added).

"When aqueous gellan solution is carefully added into an aqueous chitosan solution at pH5-5.5 at 50°C without mixing, a film of the polyion complex is formed at the interface. When this is removed without stirring, it is instantly and continuously replaced. When this film is withdrawn from a liquid surface and is hung up over a glass rod, regularly droplet form along the fiber line in the wet states" (page 288, left column).

After the intact wet droplet fiber is dried in air, a strong fiber forms. The inside of the Amaike fiber is gellan and the outside of it is coated with chitsosan. This fiber is a kind of polyion complex structure; that is, the outside layer is chitosan, and the inside layer is gellan. Likewise, a strong fiber is made in a similar way as described above but whose outside layer is gellan and inside layer is chitosan." (page 288, left column)

First in this regard, it is to be noted that when a catatonic (basic) polymer such as chitosan and an anionic (acidic)

polymer such as hyaluronic are contacted, they instantly form a polyion complex, which is soluble in any solvent.

Therefore, in Amaike's preparation method, a solution of anionic polymer (or cationic polymer) must be carefully added to a solution of cationic polymer (or anionic polymer) without mixing to obtain a film or fiber. That is, when a solution of anionic polymer (or cationic polymer) is very quietly put on a solution of cationic polymer (or anionic polymer), a polyion complex is formed as a film at the interface of the solutions. When the film is quietly pulled up with a glass rod, a fiber is formed. If the addition of the solution is carried out less carefully or with the mixing, the film, and therefore the fiber of the polyion complex, can never be obtained. It is further noted that a solution of anionic polymer (or cationic polymer) is added to a solution of cationic polymer (or anionic polymer) in Amaike's preparation method.

On the other hand, in the present invention a chitosan solution is wet spun to form the chitosan fiber which is a solid. The chitosan fiber obtained is then reacted with biodegradable acidic biopolymer in a solution to form the fiber wherein the inner part of the fiber comprises chitosan and the surface of the fiber is covered by a complex of chitosan and acidic polymer. Thus the method of the present invention is quite different from Amaike in that chitosan fiber (solid) is contacted with a solution of anionic biopolymer in the present invention, whereas a solution containing chitosan is contacted with a solution containing anionic polymer in the Amaike's preparation method. The resultant fiber is also quite

different in that the interior is chitosan and the surface is complex.

In addition, the present invention as called for in new Claim 16 is advantageous over Amaike's fiber in that Amaike's method is not appropriate for large scale production. The chitosan/acidic polymer fiber of the present invention is formed after the formation of chitosan fiber, whereas, in the Amaike method, it is possible to make film and hence fiber only when the solution of chitosan is very carefully, i.e. very quietly, added to the solution of anionic polymer so as not to move both the solutions. This would be practically impossible on a large scale production of fiber. Preparation of the fiber by the Amaike's method would be possible only in a beaker scale in a laboratory. The present invention is not thus anticipated by Amaike.

The fiber of the present invention has the mechanical strength which is more or less at the same level as rayon fiber (see Tables 3 and 4 of the present specification).

Withdrawal of the rejection is in order and is respectfully requested.

Claims 1, 2 and 5-8 have been rejected under §102 as anticipated by EP 0 544 259 in the name of Tadashi Uragami et al, document AG, and there identified by the name of the applicant, Lignyte, this document hereinafter being referred to as "Uragami". The rejection is respectfully traversed.

Uragami describes the preparation of the fiber as follows:

"A first aqueous solution of the alkalimetal salt of hyaluronic acid and a second organic acid aqueous solution of the biocompatible high molecular compound are prepared. One of the first and the second solution is introduced into the other solution through a nozzle, so that an aqueous solution including polyion complex fibers is obtained. The polyion fibers are removed from the aqueous solution to form a wet sheet of the polyion complex fibers, and then the wet sheet is dried to obtain the fiber-sheet of the polyion complex" (page 3, lines 40-45);

As is apparent from the description of Uragami, an aqueous solution of hyaluronic acid is introduced into an aqueous solution of the high molecular compound such as chitosan through a nozzle. That is, an aqueous solution of hyaluronic acid contacted with an aqueous solution of the high molecular compound such as chitosan with both the aqueous solutions being moved. Therefore, the resultant fiber consists of polyion complex as a whole. The fiber cannot have the structure in which the inner part of the fibers comprises chitosan and the surface of the fibers are covered by the complex of chitosan and hyaluronic acid, which structure the fiber of the present invention has. In addition, only short fibers are obtained by Uragami.

On the other hand, in the present invention a chitosan solution is wet spun to form a fiber which is solid. The chitosan fiber obtained is then reacted with biodegradable acidic biopolymer in a solution to form a fiber wherein the inner part of the fiber comprises chitosan and surface of the fiber is covered by a complex

of chitosan and acidic fiber. Long fibers can be obtained in the present invention.

The fiber by Uragami is thus quite different from the present invention. Uragami neither discloses, teaches nor suggests the present invention.

Withdrawal of the rejection is in order and is respectfully requested.

Claims 1, 2 and 5-8 have been rejected as obvious under §103 from Amaike in view of Uragami. This rejection is respectfully traversed.<sup>1</sup>

Applicants do not see how a person skilled in the art could possible combine these two references as their methods of producing fibers are inconsistent and incompatible. These two patents can be combined only in view of applicants' disclosure, which of course was not available to the person of ordinary skill in the art at the time the present invention was made.

Amaike's method for preparing fiber is common with Uragami's method for preparing fiber only in that the aqueous solution of cationic polymer is directly contacted with an anionic polymer, as stated above.

On the other hand, the fiber of the present invention is formed by contacting chitosan fiber (solid) with aqueous solution of acidic biopolymer. This gives a different result, i.e. a different fiber, as pointed out above.

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<sup>1</sup> This rejection is clearly and certainly inconsistent with the two anticipation rejections. If it takes a combination of the two references together to make obvious the claimed subject matter, then clearly the anticipation rejections are incorrect and improper.



In addition, a first aqueous solution is quietly contacted with a second aqueous solution without the movement of the solutions in the Amaike's method, whereas a first aqueous solution is contacted with a second aqueous solution with moving in the Uragami's method. Both the methods for preparing fiber are thus quite different from each other.

Accordingly, those skilled in the art would not have been motivated to even attempt to combine both the methods. Even if the methods were somehow combined, it is apparent that the resultant combination would not reach the present invention.

Withdrawal of the rejection is in order and is respectfully requested.

Applicants note reference at the middle of page 11 of the Office Action to what is stated to be "pertinent prior art not relied upon in the rejections". These have not been officially cited of record on the form PTO-892. Applicants respectfully request the examiner to officially make these documents of record so that they will appear on the face of the printed patent which issues from the present application.

The prior art documents of record and not relied upon by the PTO have been noted, along with the implication that such documents are deemed by the PTO to be insufficiently material to warrant their application against any of applicants' claims.

Applicants believe that all issues raised in the Official Action have been addressed above in a manner that should lead to

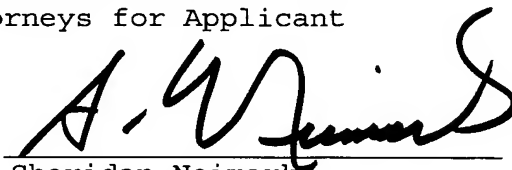
Appln. No. 10/519,541  
Amd. dated January 8, 2007  
Reply to Office Action of October 6, 2006

patentability of the present application. Favorable consideration  
and early formal allowance are respectfully requested.

Respectfully submitted,

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By

A handwritten signature in black ink, appearing to read "A. Neimark", written over a horizontal line.

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ACLM/"A fiber according to claim 1": 2066 patents.

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PAT. NO.	Title
1 <a href="#">7,158,706</a>	<a href="#">Optical fiber</a>
2 <a href="#">7,158,705</a>	<a href="#">Optical fiber with birefringence and large mode field diameter</a>
3 <a href="#">7,158,704</a>	<a href="#">Image fiber</a>
4 <a href="#">7,155,098</a>	<a href="#">Method of manufacturing optical fiber preform using modified chemical vapor deposition including dehydration and dechlorination process and optical fiber manufactured by the method</a>
5 <a href="#">7,150,913</a>	<a href="#">Sizing agent for carbon fiber, aqueous dispersion of the same, carbon fiber treated by sizing, sheet comprising the carbon fiber, and carbon fiber-reinforced composite material</a>
6 <a href="#">7,150,911</a>	<a href="#">Electrical insulating vapor grown carbon fiber and method for producing the same, and use thereof</a>
7 <a href="#">7,150,840</a>	<a href="#">Graphite fine carbon fiber, and production method and use thereof</a>
8 <a href="#">7,142,758</a>	<a href="#">Optical fiber with quantum dots</a>
9 <a href="#">7,139,458</a>	<a href="#">Double clad rare earth doped fiber</a>
10 <a href="#">7,135,228</a>	<a href="#">Elastic, heat and moisture resistant bicomponent and biconstituent fibers</a>
11 <a href="#">7,135,225</a>	<a href="#">Acrylic synthetic fiber improved in styleability</a>
12 <a href="#">7,131,886</a>	<a href="#">Method of producing fiber, and methods of producing electron-emitting device, electron source, and image display device each using the fiber</a>
13 <a href="#">7,130,514</a>	<a href="#">High SBS threshold optical fiber</a>
14 <a href="#">7,128,971</a>	<a href="#">Coated glass fibers for reinforcing rubber</a>

Attachment A

- 15 [7,126,748](#)  [Optical fiber, optical fiber module, and Raman amplifier](#)
- 16 [7,123,803](#)  [Optical fiber and optical transmission line and optical communication system including such optical fiber](#)
- 17 [7,122,598](#)  [Nematic elastomer fiber with mechanical properties of a muscle](#)
- 18 [7,122,248](#)  [Security articles](#)
- 19 [7,120,343](#)  [Optical fiber with epoxidized polyolefin based coating](#)
- 20 [7,120,337](#)  [Fiber optic pigtail design for reducing insertion loss and insertion loss ripple](#)
- 21 [7,116,472](#)  [Rare-earth-doped optical fiber having core co-doped with fluorine](#)
- 22 [7,115,311](#)  [Anti-static woven flexible bulk container](#)
- 23 [7,114,858](#)  [Laser based ignition system for natural gas reciprocating engines, laser based ignition system having capability to detect successful ignition event; and distributor system for use with high-powered pulsed lasers](#)
- 24 [7,113,675](#)  [Optical fiber tip diffuser and method of making the same](#)
- 25 [7,110,651](#)  [Optical fiber having enhanced separation of higher-order modes](#)
- 26 [7,110,647](#)  [Multimode polarization maintaining double clad fiber](#)
- 27 [7,108,912](#)  [Polytetrafluoroethylene fiber and method for manufacturing the same](#)
- 28 [7,106,934](#)  [Non-zero dispersion shifted optical fiber](#)
- 29 [7,104,704](#)  [Transmission apparatus using a plastic fiber](#)
- 30 [7,103,251](#)  [Dispersion flattened NZDSF fiber](#)
- 31 [7,101,623](#)  [Extensible and elastic conjugate fibers and webs having a nontacky feel](#)
- 32 [7,101,622](#)  [Propylene-based copolymers, a method of making the fibers and articles made from the fibers](#)
- 33 [7,099,545](#)  [Single-mode optical fiber](#)
- 34 [7,099,544](#)  [High SBS threshold NZDS optical fiber](#)
- 35 [7,099,543](#)  [High SBS threshold NZDS optical fiber](#)
- 36 [7,097,904](#)  [Porous fiber](#)
- 37 [7,097,820](#)  [Continuous fiber of single-wall carbon nanotubes](#)
- 38 [7,095,932](#)  [Chromatic dispersion compensating optical fiber](#)
- 39 [7,094,466](#)  [3GT/4GT biocomponent fiber and preparation thereof](#)
- 40 [7,088,900](#)  [Alkali and fluorine doped optical fiber](#)
- 41 [7,088,897](#)  [Double-coated optical fiber](#)
- 42 [7,087,301](#)  [Bicomponent fibers of syndiotactic polypropylene](#)
- 43 [7,085,465](#)  [Optical fiber and method of measuring coefficient of kinetic friction of optical fiber](#)
- 44 [7,085,464](#)  [Optical fiber having high nonlinearity](#)
- 45 [7,085,462](#)  [Optical fiber, optical fiber module and optical amplifier](#)
- 46 [7,083,854](#)  [Fibers from polymer nanoclay nanocomposites by electrospinning](#)
- 47 [7,082,243](#)  [Large effective area high SBS threshold optical fiber](#)
- 48 [7,082,242](#)  [Multiple core microstructured optical fibers and methods using said fibers](#)
- 49 [7,082,236](#)  [Fiber-based displays containing lenses and methods of making same](#)
- 50 [7,081,299](#)  [Polypropylene fibers and fabrics](#)

# GELLAN GUM

Prepared at the 49th JECFA (1997), published in FNP 52 Add 5 (1997)  
superseding specifications prepared at the 46th JECFA (1996), published in FNP  
52 Add 4 (1996)

## SYNONYM

INS No. 418

## DEFINITION

Gellan gum is a high molecular weight polysaccharide gum produced by a pure culture fermentation of a carbohydrate by *Pseudomonas elodea*, purified by recovery with isopropyl alcohol, dried, and milled. The high molecular weight polysaccharide is principally composed of a tetrasaccharide repeating unit of one rhamnose, one glucuronic acid, and two glucose units, and is substituted with acyl (glyceryl and acetyl) groups as the O-glycosidically-linked esters. The glucuronic acid is neutralized to a mixed potassium, sodium, calcium, and magnesium salt. It usually contains a small amount of nitrogen containing compounds resulting from the fermentation procedures.

## C.A.S. number

71010-52-1

## Formula weight

Approximately 500,000

## Assay

Attachment B

Yields, on the dried basis, not less than 3.3% and not more than 6.8% of carbon dioxide (CO<sub>2</sub>).

## DESCRIPTION

Off-white powder

## FUNCTIONAL USES

Thickening agent, gelling agent, stabilizer

## CHARACTERISTICS

### IDENTIFICATION

#### *Solubility*

Soluble in water, forming a viscous solution; insoluble in ethanol

#### Gel test with calcium ion

Add 1.0 g of the sample to 99 ml of water, and stir for about 2 h, using a motorized stirrer having a propeller-type stirring blade. Draw a small amount of this solution into a wide bore pipet and transfer into a 10% solution of calcium chloride. A tough worm-like gel will be formed immediately.

#### Gel test with sodium ion

Add 1.0 g of the sample to 99 ml of water, and stir for about 2 h, using a motorized stirrer having a propeller-type stirring blade. Add 0.50 g of sodium chloride, heat to 80° with stirring, and hold at 80° for 1 min. Allow the solution to cool to room temperature. A firm gel is formed.

## PURITY

***Loss on drying***

Not more than 15% (105°, 2½ h)

***Nitrogen***

Not more than 3%

**Isopropyl alcohol**

Not more than 750 mg/kg

See description under TESTS

**Microbiological criteria**

Total plate count: Not more than 10,000 colonies per gram

*E. coli*: Negative by test

*Salmonella*: Negative by test

Yeasts and moulds: Not more than 400 colonies per gram

See description under TESTS

***Lead***

Not more than 2 mg/kg

Prepare a sample solution as directed for organic compounds in the Limit Test and determine the lead content by atomic absorption

<http://www.cybercolloids.net/library/jecfa/index.php?submit=showspec&gum=additive-0660>

## Gellan Gum

• 71010-52-1 •

**Definition** Gellan Gum mainly consists of polysaccharides, obtained from cultured solution of *Pseudomonas* species.

**Content** Gellan Gum, when dried, contains 85.0 • 108.0 % of gellan gum .

**Description** Gellan Gum occurs as a whitish to brownish powder, and has slightly particular odor.

**Identification** (1) Gellan Gum is soluble in water and forms viscous solution.

(2) To 1 g of Gellan Gum, add 100 ml of water, and stir for 2 hours. Take small amount of the solution into the pipette, add the solution to 10 % calcium chloride solution, immediately a linear gel is formed.

(3) To 90 ml of the solution obtained under (2), add 0.50 g of sodium chloride. Heat the solution to 80 • • while stirring and allow for 1 minutes. Cool to room temperature without stir, a gel is formed.

**Purity** (1) Total Nitrogen Not more than 3.0 % (1.0 g, Kjeldahl method).

(2) Heavy metals Not more than 20 µg/g as Pb (1.0 g, Method 2, Control solution Lead Standard Solution 2.0 ml).

(3) Lead Not more than 2.0 µg/g as Pb (5.0 g, Method 1).

(4) Arsenic Not more than 4.0 µg/g as As<sub>2</sub>O<sub>3</sub> (0.50 g, Method 3, Apparatus B).

**Loss on Drying** Not more than 15.0 % (105 • ; 2.5 hours).

**Ash** Not more than 16.0 % (calculated on the dried basis).

**Microbial Limits** Proceed as directed under the Microbial Limit Tests. The total viable aerobic count is not more than 10,000/g and no *Escherichia coli* is observed.

**Assay** Take about 1.0 g of diatomaceous earth for chromatography, place into a glass filter(1G3), and spread uniformly. Dry at 105 • •for 5 hours, allow to cool in a desiccator, and weigh accurately. Weigh accurately about 0.2 g of dried Gellan Gum, add 50 ml of water, and dissolve while stirring in a water bath. Add 200 ml of isopropyl alcohol warmed at 60 • 70 • •previously, mix well, and allow to stand over night. Filter the gained precipitate by the glass filter as mentioned above, using isopropyl alcohol. Wash the residue 3 times with each 20 ml of 78% vol isopropyl alcohol, and wash twice with each 10 ml of 78% vol isopropyl alcohol. Dry the desiccator over night at 105 • ; and weigh accurately. Calculate the content by the following formula

Content of gellan gum

Attachment C



$$= \frac{\text{Weigh (g) of the residue}}{\text{Weight (g) of the sample}} \times 100 (\%).$$